K033599

SEP 16 2004

510(k) SUMMARY FOR FREEDOM OF INFORMATION

ONSI™-56 (onsifocon A) RIGID GAS PERMEABLE
SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS
FOR DAILY WEAR

1. Submitted by: The Lagado Corporation
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Englewood, CO 80110

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Chicago, IL 60601
(312) 553-0828

2. Date prepared: June 30, 2004

3. Device:
Common Name ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

Trade Name ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

4. Classification Class II (Performance Standards)
21 CFR 886.5916 (b) (1)
Rigid Gas Permeable Contact Lens for Daily Wear

5. Substantial Equivalence This product is substantially equivalent to other currently marketed rigid lenses, such as Oxycon (wilofocon A) Rigid Gas Permeable Contact Lenses

6. Device Description The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are available in spherical designs in the clear untinted or blue, green, gray, or blue-violet tinted varieties and blue tint with UV-blocker. Each is a shell of the following dimensions.

Spherical Contact Lens:

Horizontal Lens Size:	6.5 mm to 11.50mm
Base Curve:	6.50mm to 9.50mm
Distance Powers:	+12.00D to -20.00D
Center Thickness:	
for low minus	0.05mm to 0.30mm
for plus	0.10mm to 0.70mm

Aspheric Lens

Eccentricity	0 to 1.5
Peripheral Curves	0.1 to 1.0mm

Toric Lens

Axis	1 to 180 degrees in 1 degree steps
Cylinder power	0.50 to 4.00D

Translating Bifocal Contact Lens:

Horizontal Lens Size:	8.00mm	to	10.50mm
Base Curve:	6.50mm	to	8.50mm
Distance Power:	+12.00D	to	-20.00D
Add Power	1.00	to	4.00D

The lens material, onsifocon A, is trifluoroethyl methacrylate polymer with tris (trimethylsiloxy)methacryloxypropylsilane 3-trimethoxysilylpropylmethacrylate methacrylic acid 1,3-bis(3- methacryloxypropyl)tetrakis(trimethylsiloxy)disiloxane ethylene glycol dimethacrylate 2-hydroxyethyl methacrylate N-vinylpyrrolidone. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-violet contain D&C Green No. 6 and D&C Violet No. 2; the blue-UV lenses contain D&C Green No 6 and a UV absorber, NORBLOC 7966. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

7. Intended use

The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism.

The lenses may be disinfected only by using chemical disinfection

8. Comparison to predicate devices: see following table

SUBSTANTIAL EQUIVALENCE

	OXYCON (wilofocon A)	ONSI™-56 (onsifocon A)
Water Content	<1%	<1.0%
Oxygen Permeability	$26x10^{-11}$ Fatt Units(1990)	56.2 ANSI units
Refractive Index	1.44	1.452
Hardness	D/89 (Shore)	D/85 (Shore)
Specific Gravity	1.25	1.206
Residual Monomers		no leachable monomers detected
Wetting Angle	23.0∀2 (CLMA method)	7.25E∀1.55 (sessile drop method)
Mechanical (flexural) Strength		2698psi

		OXYCON (wilofocon A)	ONSI™-56 (onsifocon A)
Light Transmittance	clear		>95% T
	blue		>70% T
	green	93%	>70% T
	gray	87%	>70% T
	blue-violet		>70% T
	blue UV		>70% T (400-780nm) 0% T (200-380nm)

Introduction

The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic, or presbyopic and which may exhibit corneal astigmatism.

Contained in the submission are comparisons of the product to the predicate device, information on the chemistry and manufacturing, results of toxicological tests, and the report of a clinical trial of 37 subjects, who have used the product over a period of three months.

I. Chemistry and Manufacturing

The lens material, onsifocon A, is trifluoroethyl methacrylate polymer with tris (trimethylsiloxy)methacryloxypropylsilane 3-trimethoxysilylpropylmethacrylate methacrylic acid 1,3-bis(3- methacryloxypropyl)tetrakis(trimethylsiloxy)disiloxane ethylene glycol dimethacrylate 2-hydroxyethyl methacrylate N-vinylpyrrolidone.

The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-violet lenses contain D&C Green No 6 and D&C Violet No 2; the blue-UV lenses contain D&C Green No 6 and a UV absorber, NORBLOC 7966. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

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Distance Power:	+12.00D	to	-20.00D
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II. Toxicology

The toxicological testing is summarized below. The lens material was shown to be non-toxic in all tests.

A. Agar Overlay Cytotoxicity:

The ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lens material was tested in a direct contact cytotoxicity assay. The lenses were noncytotoxic.

B. Systemic toxicity:

Saline and cottonseed oil extracts of the ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lens material were evaluated for systemic toxicity by intraperitoneal (ip) or intravenous (iv) injection in healthy mice, 50ml/kg body weight. The animals were observed over a 72 hour period, and showed no difference from control animals. The lenses passed the test requirements, that there be no difference between the response of test and control animals.

C. Acute Ocular irritation:

Saline and cottonseed oil extracts of the ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lens material were evaluated for ocular irritation by instillation into the inferior ocular cul-de-sac of rabbits. The eyes were examined over a 72 hour period and showed no irritation.

III. Microbiology

The material has a water content less than 1%, and is therefore exempt from the microbiological requirements for hydrophobic contact lenses. Bioburden testing will be performed periodically on finished product.

IV. Clinical Studies

A clinical trial of 3 months usage of the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical Contact Lenses by 37 subjects, wearing lenses on a daily wear schedule, showed that the product is substantially equivalent to other lenses available on the market. Comparison was made to historical controls wearing wilofocon A. The clinical summary follows.

The study was conducted over 3 months of wear, subjects being seen initially, and after 1, 2 weeks and 1, 2 and 3 months.

Three (3) investigators enrolled a total of 37 test subjects. The age range of the test population was from 15 to 58, with 27 (73%) females and 10 (27%) males. Of the 37 subjects, 36 (97%) completed 3 months of wear, and 1 (3%) discontinued.

FINDINGS

a. SAFETY:

(1) Adverse Reactions

The FDA regulations for medical devices (21 CFR 812.3) define an unanticipated adverse device effect as:

"any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that related to the rights, safety or welfare of the subject"

There were no adverse events during this study.

(2) Slit Lamp Findings:

A positive slit lamp finding is a routinely occurring complication that can be expected with or without the presence of contact lenses. The degree of severity may range from very slight, representing no medical concern, to serious, requiring medical treatment.

The following table shows the incidence of slit lamp findings at the initial and final visits.

INCIDENCE OF SLIT LAMP FINDINGS

FINDING	INITIAL	FINAL
NO FINDINGS[a]	90.5	95.8
EDEMA[b]	0.0	0.0
NEOVASCUL.	1.4	0.0
STAINING	5.4	3.2
HYPEREMIA	1.4	0.0
PALPEBRAL ABNORM.	1.4	0.0
OTHER	0.0	0.0

[a] Percent of eyes examined with no findings, initial or final scheduled follow-up visits only

[b] Percent of eyes with finding, initial or final scheduled follow-up visits only

(3) Symptoms, Problems and Complaints:

Symptoms, problems and complaints were reported by the investigators at each visit. "No symptoms" were reported at 76% of the scheduled follow up visits, and at all interim visits. The most frequent symptoms were of lens awareness and reading problems, followed by need for cleaning and dryness. The "other" symptoms in the population were: tired or fatigue (4 reports, 4 eyes of 2 subjects); cloudy or fogging (8 reports, 4 eyes of 2 subjects); scratchy sensation or itch (4 reports, 4 eyes of 2 subjects); difficult to remove (6 reports, 2 eyes of 1 subject).

SELECTED SYMPTOMS, PROBLEMS AND COMPLAINTS

SYMPTOM	INCIDENCE
NONE[a]	75.7%
LENS AWARENESS[b]	5.7%
READING PROBLEMS	5.5%
NEED FOR CLEANING	5.2%
DRYNESS	4.6%

[a] Percent of eyes examined with no findings, regularly scheduled visits only
[b] Percent of eyes with finding, regularly scheduled visits only

(4) Discontinuations:

Throughout the study, 1 subject (3%) was discontinued.

b. EFFICACY:

(1) Visual Acuity:

All eyes had a final visual acuity within 1 line of the initial best corrected acuity.

(2) Wear Time:

Wear time remained essentially unchanged over the three months of the study, indicating continuing comfort and cleanliness with the investigational lenses.

(3) Lens Replacements:

A total of 10 lenses were replaced during the study, 6 for visual acuity, 5 of the 6 within the first month. These results indicate that the lenses are effective in the correction of myopia.

Gender Comparisons:

The overall population was 73% female, 27% male. No further gender analysis was warranted.

OVERALL CONCLUSION OF THE CLINICAL STUDY:

The data of the clinical trial demonstrate the safety and efficacy of the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical Contact Lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

The Lagado Corporation
c/o John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K033599
Trade/Device Name: ONSI™ – 56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: July 7, 2004
Received: July 8, 2004

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) K033599

DEVICE NAME ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

INDICATIONS FOR USE

The ONSIJ-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism.

The lenses may be disinfected only by using chemical disinfection

Prescription Use X (Part 21CFR 801 Subpart D) OR Over-The-Counter-Use (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K033599